REMARKS

In reply to the Office Action Mailed April 28, 2004, Applicants amended claim 1 and cancelled claims 4, 5 and 12-14. Claims 1-3 and 6-11 are presented for examination.

Enablement Rejection

The Examiner rejected claims 1-11 under 35 U.S.C. §112, first paragraph for purportedly failing to satisfy the enablement requirement.[1] In *In re Wands* 858 F.3d 731 (Fed. Cir. 1998), the United States Court of Appeals for the Federal Circuit described the factors to be considered and balanced when determining whether a disclosure satisfies the enablement requirement. Each of these factors is discussed below with respect to the pending claims.

The nature of the invention:

The claims cover compound libraries that include at least 100 compounds, where: a.) the compounds are pharmaceutical compounds of molecular weight of less than 1000 Daltons; b.) each compound within the library is stored in the presence of a cyclodextrin; and c.) the cyclodextrin concentration is 20-200mM.

The level of one of ordinary skill in the art:

The level of skill of one of ordinary skill in the art is relatively high. In general, one of ordinary skill in the art would likely have a Ph.D. in chemistry and would be familiar with compound libraries.

The state of the prior art:

No one has previously disclosed or suggested the compound libraries covered by the pending claims.

The breadth of the claims:

The limitations of the pending claims are noted above.

---

[1] Applicants cancelled claims 4 and 5, so the rejection of these claims should be withdrawn.

The level of predictability in the art:

As discussed below, in view of the knowledge of one skilled in the art, the present application discloses sufficient information to allow one of ordinary skill in the art to successfully implement the compound libraries covered by the pending claims.

The existence of working examples:

Applicants submitted appropriate experimental data for preparing a compound library with 80 compounds and a library with 1600 compounds.

The amount of direction provided by the inventor:

The present application provides sufficient direction to one of ordinary skill in the art to successfully implement the compound libraries covered by the pending claims. Applicants provided guidance with respect to examples of chemical classes that can be included in the libraries and the number of chemical classes that can be included in the compound libraries. (*See, e.g., Specification* at page 3, lines 20-27.) Applicants also provided guidance with respect to various other features of the technology, such as the number of compounds in the libraries (*see, e.g., id.* lines 8-14), the molecular weight of the compounds in the libraries (*see, e.g., id.* lines 17-19), the concentration of cyclodextrin in the libraries (*see, e.g., id.* lines 28-31), a particular type of cyclodextrin that can be used (*see, e.g., id.* at page 7, line 30-page 8, line 17), and the form of the compound libraries (*see, e.g., id.*). Applicants provided further guidance regarding the general structural and chemical properties of cyclodextrins. (*See, e.g., id.* at page 5, lines 23-24.)

The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

As amended, the claims are limited to pharmaceutical compounds having a molecular weight of 1000 Daltons or less, which generally corresponds to the size of drug molecules. As known to those skilled in the art, in general such compounds are partners for forming complexes with cyclodextrins. For example, Szejtli, *Chem. Rev.* **1998**, 98, 1743, 1749 (Szejtli) discloses that:

> [m]ost drug molecules are ideal complex-forming partners for cyclodextrins, because their polarity, molecular mass, and structure enable them to get included in the CD cavity.

Szejtli also provides an explanation of how compounds interact with cyclodextrin (along with a pictorial example), and a relatively detailed discussion regarding the complexing of drug molecules and cyclodextrins. (*Id.* at 1747-48.)

In view of the foregoing, Applicants request reconsideration and withdrawal of this rejection.

§102 Rejection

The Examiner rejected claims 1-11 under 35 U.S.C. §102 as being anticipated by Henco *et al.* ("Henco").[2] However, Henco is not prior art to the present application under 35 U.S.C. §102(a) because, while the present application has a priority date of August 24, 1999, Henco was not published until October 6, 1999. Applicants will submit a certified copy of the foreign priority application in the near future.[3] This document demonstrates that the subject matter covered by claims 1-11 is supported by the foreign priority application. Thus, Henco is not prior art to claims 1-11. Applicants therefore request reconsideration and withdrawal of this rejection.

§103 Rejections

The Examiner rejected claims 1-9 and 11 under 35 U.S.C. §103 as being obvious over the combination of Szente *et al.* ("Szente"), Tabushi *et al.* ("Tabushi") and Applicants' purported admission in the specification.[4]

The pending claims cover compound libraries having at least 100 compounds where each compound is stored in the presence of a cyclodextrin having a concentration of 20-200 mM.

Szente discloses that certain cyclodextrins can apparently prevent degradation of some compounds. (*See* Szente at Summary.) Applicants do not concede that it is proper to characterize Szente as disclosing compound libraries. However, assuming *arguendo*, that Szente does disclose compound libraries, Szente does not disclose a cyclodextrin concentration of 20-

[2] Applicants cancelled claims 4 and 5, so the rejection of these claims should be withdrawn.
[3] No translation is required as the priority document is in English.
[4] Applicants cancelled claims 4 and 5, so the rejection of these claims should be withdrawn.

200 mM, as required by the pending claims. Nor does Szente provide any suggestion to use such a concentration. Rather, Szente seems to have found concentrations that work for his intended purposes. (*See, e.g., id.*) After reading this, one skilled in the art would not have been motivated to modify Szente's concentrations to provide the concentrations required by the pending claims.

Further, even one skilled in the art were somehow motivated to modify Szente's cyclodextrin concentration, consideration would not have been given to Tabushi because Tabushi is directed to an entirely different use of cyclodextrins from Szente. Tabushi discloses the use of cyclodextrins as a reaction catalyst for particular compounds relating to vitamin K. (*See* Tabushi at Abstract.) This has nothing whatsoever to do with the use of cyclodextrins in compound libraries.

Moreover, to the extent that Applicants' specification is available as prior art, Applicants' specification does not cure the infirmities of Szente and Tabushi. For example, the portion of Applicants' specification that is available as prior art does not disclose or suggest compound libraries where each compound is stored in the presence of a cyclodextrin having a concentration of 20-200 mM.

Neither Szente, Tabushi nor Applicants' specification (to the extent that it is available as prior art), alone or in combination, disclose or suggest the compound libraries covered by the claims, and there is no suggestion to combine these references to provide such compound libraries. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1-9 and 11 under 35 U.S.C. §103 as being obvious over either the combination of Szente, Tabushi and Applicants' specification.

The Examiner also rejected claims 1-11 under 35 U.S.C. §103 as being obvious over the combination of Szente, Tabushi, U.S. Patent No. 5,985,310 (Castillo) and Applicants' specification.[5]

The combination of Szente, Tabushi and Applicants' specification is discussed above where it is demonstrated that this combination of references does not render the pending claims obvious. Castillo does not cure the infirmities of this combination of references. First, Castillo

[5] Applicants cancelled claims 4 and 5, so the rejection of these claims should be withdrawn.

does not disclose or suggest the compound libraries covered by the pending claims. In addition, one skilled in the art would not have been motivated to combine Tabushi and Castillo because, whereas Tabushi discloses the use of cyclodextrins as a reaction catalyst for particular compounds relating to vitamin K (*see* Tabushi at Summary), Castillo is interested in finding a preservative that works in the presence of cyclodextrin. (*See* Castillo at Abstract.) Thus, neither Szente, Tabushi, Castillo nor Applicants' specification (to the extent that it is available as prior art), alone or in combination, disclose or suggest the compound libraries covered by the claims. There is no suggestion to combine these references to provide such compound libraries. Applicants therefore request reconsideration and withdrawal of the rejection of claims 1- 11 under 35 U.S.C. §103 as being obvious over either the combination of Szente, Tabushi, Castillo and Applicants' specification.

Applicants believe the application is in condition for allowance, which action is requested.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: August 26, 2004

Catherine M. McCarty Reg. No. 54,301

For: Janis K. Fraser, Ph.D., J.D.
Reg. No. 34,819

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20900101.doc